REMARKS

Applicants acknowledge that the present Office Action presents a new ground of rejection, and applicants appreciate the implied indication by the Office that the rejections that employ Babayan et al. U.S. Patent No. 4,952,606 of the previous Office Action now have been withdrawn. Claims 1-9, 11-13, 15-25, 27, 29, 35-37, 40, 41 and 43-48 now are rejected under 35 U.S.C. §103 from Babayan et al. U.S. Patent No. 3,006,771 in view of Heydinger et al. "Medium Chain Triacylglycerols" and further in view of Wester U.S. Patent No. 6,589,588 and C.F.R. §101.83 taken together.

The present Amendment revises the single independent composition claim, single method-for-making independent claim 37, and single independent method-for-using claim 40. Each such claim continues to specify that the oil compositions are **liquid** vegetable oil compositions in which the interesterified liquid structured lipid component is a reaction product of **between about 30 and 60 weight percent medium chain** vegetable triglyceride **and between about 40 and 70 weight percent long chain** domestic vegetable oil triglyceride. In addition, each independent claim specifies that said medium chain triglyceride is selected from the group consisting of caprylic triglyceride, capric triglyceride, and combinations thereof, and specifies the domestic oil is selected from the group consisting of soybean oil, corn oil, cottonseed oil, canola oil, olive oil, peanut oil, safflower oil, sunflower oil, oil from grain plants, and combinations thereof. Support is found in original claims 7 and 18 and elsewhere in the originally filed application. Also, dependent claims 7, 18, 19, 29, 35 and 36 are amended or cancelled to be consistent with other claim revisions.

Applicants have studied Babayan '771 and understand that this is the Babayan to which the Office refers throughout the present Office Action. If this is not correct, clarification is respectfully requested.

Applicants note the Office finds that Babayan '771 teaches in effect that the "extent of medium chain fatty acids is over 35%." Applicant defines medium chain fatty acids (MCTs) in their claims as capric and caprylic components. Babayan disclose what he refers to as "short chain" fatty acid triglycerides having from 6 to 10 carbon atoms. *See* the first column of the first page, at lines 46-50. The fatty acids that fall within this Babayan carbon link range (and that Babayan '771 identifies) are capric and caprylic acids. Capric is C10, and caprylic is C8.

Applicants claim caprylic and capric MCTs, more specifically at least about 30 weight percent MCTs.

Lines 41-42 in column 2 of Babayan teach a range from about 10 to 25% capric and caprylic acids. This same range is specified in claim 1 in column 4 of Babayan, and this is the highest level of capric and caprylic taught by Babayan. The Office appears to refer to Example 1 of Babayan '771. This teaches that the total amount of mixed lower fatty acid triglycerides was 51 pounds. The total weight of the reactants is 506.5 pounds. Thus, the mixed lower fatty acid triglycerides are at a level of just over 10 weight percent, which is far below the maximum of 25% in the Babayan '771 ranges.

Accordingly, as applicants understand, Babayan '771, it teaches total capric.and caprylic MCTs at a maximum amount of 25%. Applicants currently claim that the level of these MCTs is between about 30 and 60 weight percent.

Babayan '771 also discusses long-chain fatty acids having 16 and 18 carbon atoms, for example, at lines 56-59 in the first column of the first page of that patent. The paragraph beginning at line 39 in column 2 of Babayan '771 lists lauric (C12) and myristic (C14), as well as palmitic (C16) and stearic (C18). Not all of these fall within the claimed domestic oil long chains of at least C16 in length. The Babayan '771 teaching of C16 and C18 is 15% to 60%. This same range is in claim 1 of Babayan '771.

However, this broadest range for palmitic and stearic in Babyan '771 is for the intersterified fat composition, not of the reactant charge. Babayan '771 clearly teaches multiple times that the reactant charge contains a large quantity of coconut oil. For example, lines 32-36 in column 2 teach the triglycerides intersterified with coconut type oil are from **5% to 30%** "short chain fatty acid triglycerides," which are defined in column 1, lines 46-50, as 6 to 10 carbon atoms. As taught at lines 44-46 of column 1, the coconut type oil has 6 to 18 carbon atoms. As well known in the art, the 6 to 18 carbon atoms range is that of coconut oil. Putting these passages in columns 1 and 2 together shows **Babayan '771 teaches the coconut oil C6 to C18 reactant charge** (assuming no other charge except the C6 to C10 "short chain" fatty acids) **is 70 to 95%**.

Applicants claim 40 to 70 weight percent of domestic oils. The art knows domestic oils do not include the tropical oils such as coconut oil or palm kernel oil. To be sure this distinction is perfectly clear, the independent claims now specify the list of domestic oils found in the application as filed.

Accordingly, Babayan '771 teaches a different type of oil (tropical, not long chain domestic oils specified in the claims) intersterified at a reactant level of 70 to 95%

versus the maximum of about 70% of domestic oils specified in the present claims. And this high quantity of coconut type oil is intersterified with "short chain" oils (that may encompass capric and caprylic oils) at a lower maximum level (25%) than the minimal level (30%) claimed for applicants' capric and caprylic oils.

As further evidence of this teaching of Babayan '771, Example 1 teaches 79.8% coconut oil (404/506.5 pounds), and Example 6 specifies 83% palm kernel oil and 17% triglycerides combining caprylic (C8), capric (C10), lauric (C12) and caprioic (C6).

Thus, Babayan teaches high reaction charges of non-domestic tropical oils with low reactant charges of "short chain" fatty acids to prepare a composition suitable for **margarines, not liquid compositions**.

The Office next addresses the viscosity and smoke point features in applicants' claims. However, the Babayan '771 product is for a margarine. A margarine is not a liquid composition, as applicants claim. Clearly, a liquid composition and a solid or plastic margarine composition have significantly different viscosity properties.

It appears as if the Office recognizes that Babayan '771 is deficient in its teachings regarding viscosity and smoke point, and the Office references Heydinger in this regard. The Office notes that Heydinger is cited for evidence of viscosity and smoke point for Neobee® 1814, same being an interesterified product of **butter** oil and medium chain fatty acids. In this regard, Heydinger explicitly references Babayan et al. 1990, which is identified in the notes to Heydinger as U.S. Patent No. 4,952,606, the very same Babayan reference that had been the primary reference in the previous Office Action. Applicants respectfully refer the Office to applicants' previous Amendment, which discusses Babayan '606.

Like Babayan '606, this passage of Heydinger that is relied upon by the Office teaches a reaction of **dairy fat** with medium chain fatty acids. As noted in the prior Amendment, Babayan '606 teaches one of ordinary skill in the art away from an all-vegetable structured lipid component. In the present Office Action, it is believed that the Office seeks to show the alleged obviousness of replacing the butter oil of Heydinger or Babayan '606 with coconut oil of Babayan '771. The Office states that both butter oil and hydrogenated coconut oil "would both be expected to contain a lot of saturated fatty acids," while further suggesting that interesterified products of MCTs and hydrogenated coconut oil would be expected to have a similar viscosity and smoke point as Neobee® 1814 interesterified butter oil and MCTs as in Babayan '606 or Heydinger.

However, the respective fatty acid compositions of butter oil and coconut oil are extremely different. As well known in the art, butter fat contains 3.1 percent lauric (C12), while coconut oil is primarily lauric, i.e., it contains 48.5 percent lauric fatty acid. Butter fat (C12) is primarily oleic (C18), stearic (C18) and palmitic (C16), containing 28.3 percent oleic and 26 percent palmitic, while coconut oil contains only 6.5 percent oleic, only 2.5 percent stearic and 8.4 percent palmitic. While butter fat contains 3.8 percent butyric (C4), coconut oil contains no butyric.

Applicants do not understand how one of ordinary skill in the art could expect that components having such divergent respective fatty acid compositions would be expected to have similar viscosity and smoke point properties when interesterified with MCTs. The Office has not cited any art that shows that a fat composition as in Babayan '771 has or would be expected to have a similar viscosity and smoke point to Neobee® 1814. The fact that Babayan '771 is specifically taught as being a "margarine" strongly

indicates that one looking for a liquid vegetable oil composition having the claimed viscosity would not look to margarine compositions as taught by Babayan '771.

The Wester reference is relied upon to show it is known to add phytosterol esters into foods in order to lower cholesterol. Applicants continue to acknowledge that phytosterol esters are known for lowering cholesterol in a living being, as well as to incorporate same into foods. Applicants further acknowledge that Wester indicates that phytosterols *per se* can be incorporated into cooking oil. Applicants acknowledge that the C.F.R. section relates model health claims that may be placed on food labeling. The daily dietary intake levels found at page 147 of the C.F.R. publication regulate minimum amounts (1.3 grams) of phytosterols in daily dietary intake to make the health claim specified on that page. On balance, the C.F.R. publication adds regulatory details that are not particularly relevant to applicants' invention *vis-à-vis* Wester.

It is understood that the Office takes the position that St.-Onge et al. "Consumption of a Functional Oil Rich in Phytosterols and Medium-Chain Triglyceride Oil Improves Plasma Lipid Profiles in Men" is of no value in overcoming a *prima facie* case of obviousness that arguably has been presented in the Office Action.

The Office refers to a desire by one of ordinary skill in the art to "advertise that his margarine reduces cholesterol adsorption, it would have been obvious to follow the fortification requirement set forth by the FDA in order to make this claim." However, applicants' claims recite much more than making a mere advertising claim. As pointed out in the previous Amendment, applicants' claimed invention achieves an enhanced unexpected benefit (not just an advertising claim of a benefit) when one compares the St.-Onge clinical study data with clinical testing using applicants' invention.

Data in this St.-Onge article reports reduction in LDL cholesterol, when compared to the baseline of 14%. Data of the clinical study using applicants' claimed invention (2006 publication of Rudkowska et al. "Phytosterols Mixed with Medium-chain Triglycerides and High-oleic Canola Oil Decrease Plasma Lips in Overweight Men," which accompanied the previous Amendment) show a reduction in LDL cholesterol when compared with the baseline of 21%.

More particularly, the 2006 Rudkowska publication (applicants' claimed composition and methods) and the 2003 St. Onge publication each report on clinical testing of men having a body mass index of 25-31 kg/m^2. Twenty-three of these men completed the study using applicants' invention, while thirty men were in the study of the 2003 St.-Onge publication. Each study followed a randomized crossover type of test, and each delivered the phytosterol-containing component with the same isoenergetic meal protocol of 15% protein, 40% fat and 45% carbohydrates. In the 2006 clinical study according to applicants' claimed invention, blood samples were taken at days 1, 2, 41 and 42, whereas in the 2003 St.-Onge clinical study, blood samples were taken at days 1, 28 and 29. Each analyzed the blood samples and calculated LDL cholesterol using the Friedenwald formula.

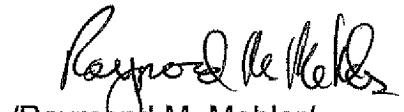
The baseline LDL for applicants' invention was 3.95, same being reduced to the end point value of 3.12, a reduction of 21%. *See* data in the table on page 393 in the "Functional Oil" columns and the "LDL-C" rows. As reported in Table 3 on page 1817 of the St.-Onge publication, the baseline for the functional oil (FctO) for LDL-C was 3.43, and the Endpoint was 2.96, a reduction of 14%. Thus, the claimed invention achieved

an increase of 7% in LDL cholesterol reduction when compared with the St.-Onge clinical study. This represents an **enhancement by a factor of one-third**.

These data show unexpected cholesterol reduction benefits when the known phytosterol ester component is delivered by way of the claimed interesterified structured lipid component. Furthermore, that structured lipid component is not disclosed, taught or suggested by Babayan '771 or by any of the secondary references. Even putting aside the unexpected cholesterol reduction benefits shown by comparing the St.-Onge data with applicants' data, applicants' claimed invention is unobvious because the combination of references simply does not reconstruct applicants' claimed invention, even with the benefit of hindsight.

Reconsideration and withdrawal of this §103 rejection are respectfully requested.

Respectfully submitted,



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